OCT 1 5 2003

H. 510(k) SUMMARY

K032223 (pg 1 of 2)

Submitted By:

Thomas J. Kardos
Vice President, Regulatory Affairs
Cook Vascular Incorporated
P.O. Box 529
Leechburg, PA 15656
Phone 724-845-8621
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May 23, 2003

Device:

Trade Name:	Cook Vascular PERFECTA™ Electrosurgical Dissection System Ergonomic Intermittent Activation Switch
Common/Usual Name:	Electrosurgical Device and Accessories
Proposed Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories 21 CFR Part 878.4400

Device Description:

The Cook Vascular PERFECTA™ EDS Ergonomic Intermittent Activation Switch is an accessory that can be used with the Cook Vascular PERFECTA™ Electrosurgical Dissection System. This device adds the option to automatically activate the Valleylab Force FX electrosurgical generator at a predetermined rate when the footswitch is depressed.

Indications for Use:

The Cook Vascular PERFECTA™ EDS Ergonomic Intermittent Activation Switch is an accessory to the Cook Vascular PERFECTA™ Electrosurgical Dissection System. The intended use of the Cook Vascular PERFECTA™ EDS Ergonomic Intermittent Activation Switch is to add the option of continuous or intermittent activation to the Electrosurgical Dissection System when the footswitch is depressed. The Cook Vascular PERFECTA™ EDS Ergonomic Intermittent Activation Switch is supplied non-sterile and is reusable.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Vascular Incorporated. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency.

Predicate Devices:

The Cook Vascular PERFECTA™ EDS Ergonomic Intermittent Activation Switch has similar indications for use and similar technological characteristics as a predicate ArthroCare Timer. The predicate device is as follows:

Predicate Device	Manufacturer	510(k)
Timer	ArthroCare	DC# K021519

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Mr. Thomas J. Kardos
Vice President, Regulatory Affairs
Cook Vascular Incorporated
Rt. 66, River Road
P.O. Box 529
Leechburg, PA 15656

Re: K032223
Trade/Device Name: PERFECTA™ EDS Ergonomic Intermittent Activation Switch
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 18, 2003
Received: July 22, 2003

Dear Mr. Kardos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032223

Device Name: PERFECTA™ EDS Ergonomic Intermittent Activation Switch

Indications For Use:

The Cook Vascular PERFECTA™ EDS Ergonomic Intermittent Activation Switch is an accessory to the Cook Vascular PERFECTA™ Electrosurgical Dissection System. The intended use of the Cook Vascular PERFECTA™ EDS Ergonomic Intermittent Activation Switch is to add the option of continuous or intermittent activation to the Electrosurgical Dissection System when the footswitch is depressed. The Cook Vascular PERFECTA™ EDS Ergonomic Intermittent Activation Switch is supplied non-sterile and is reusable.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032223

Perscription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____